Reference number(s)
1973-A, 2078-A

SPECIALTY GUIDELINE MANAGEMENT

Supprelin LA (histrelin acetate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Supprelin LA is indicated for the treatment of children with central precocious puberty (CPP).

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Central precocious puberty (CPP)

1. Authorization up to age 12 may be granted for the treatment of CPP in a female member when all of the following criteria are met:
   a. The diagnosis of CPP has been confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third generation luteinizing hormone (LH) assay.
   b. The assessment of bone age versus chronological age supports the diagnosis of CPP.
   c. The member was less than 8 years of age at the onset of secondary sexual characteristics.
2. Authorization up to age 13 may be granted for the treatment of CPP in a male member when all of the following criteria are met:
   a. The diagnosis of CPP has been confirmed by a pubertal response to a GnRH agonist test or a pubertal level of a third generation LH assay.
   b. The assessment of bone age versus chronological age supports the diagnosis of CPP.
   c. The member was less than 9 years of age at the onset of secondary sexual characteristics.

III. CONTINUATION OF THERAPY

A. Central precocious puberty (CPP)

1. Authorization up to age 12 may be granted for continuation of therapy for CPP in a female member if the member is currently less than 12 years of age.
2. Authorization up to age 13 may be granted for continuation of therapy for CPP in a male member if the member is currently less than 13 years of age.

IV. REFERENCES

1. Supprelin LA [package insert]. Malvern, PA: Endo Pharmaceuticals Solutions Inc.; May 2017.
2. Kletter GB, Klein KO, Wong YY. A pediatrician's guide to central precocious puberty. *Clin Pediatr.* 2015;54:414-424.

3. Carel J, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. *Pediatrics*. 2009;123:e752-e762.
4. Houk CP, Kunselman AR, Lee PA. Adequacy of a single unstimulated luteinizing hormone level to diagnose central precocious puberty in girls. *Pediatrics*. 2009;123:e1059-e1063.
5. Kaplowitz P, Bloch C, the Section on Endocrinology. Evaluation and referral of children with signs of early puberty. *Pediatrics*. 2016;137:e20153732.

Reference number(s)
1968-A, 2085-A

SPECIALTY GUIDELINE MANAGEMENT

TRELSTAR (triptorelin pamoate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Palliative treatment of advanced prostate cancer

B. Compendial Uses
1. Prostate cancer

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Prostate cancer
Authorization of 12 months may be granted for treatment of prostate cancer.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Trelstar [package insert]. Parsippany, NJ: Watson Pharma; January 2018.
2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 11, 2018.
3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: prostate cancer. Version 4.2018. http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed October 11, 2018.

Reference number(s)
2190-A, 2504-A

SPECIALTY GUIDELINE MANAGEMENT

TRIPTODUR (triptorelin)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Triptodur is indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP).

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Central precocious puberty (CPP)

1. Authorization up to age 12 may be granted for the treatment of CPP in a female member when all of the following criteria are met:
   a. The diagnosis of CPP has been confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third generation luteinizing hormone (LH) assay.
   b. The assessment of bone age versus chronological age supports the diagnosis of CPP.
   c. The member was less than 8 years of age at the onset of secondary sexual characteristics.
2. Authorization up to age 13 may be granted for the treatment of CPP in a male member when all of the following criteria are met:
   a. The diagnosis of CPP has been confirmed by a pubertal response to a GnRH agonist test or a pubertal level of a third generation LH assay.
   b. The assessment of bone age versus chronological age supports the diagnosis of CPP.
   c. The member was less than 9 years of age at the onset of secondary sexual characteristics.

III. CONTINUATION OF THERAPY

A. Central precocious puberty (CPP)

1. Authorization up to age 12 may be granted for continuation of therapy for CPP in a female member if the member is currently less than 12 years of age.
2. Authorization up to age 13 may be granted for continuation of therapy for CPP in a male member if the member is currently less than 13 years of age.

IV. REFERENCES

1. Triptodur [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; June 2018.
2. Kletter GB, Klein KO, Wong YY. A pediatrician's guide to central precocious puberty. *Clin Pediatr.* 2015;54:414-424.

3. Carel J, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. *Pediatrics*. 2009;123:e752-e762.
4. Houk CP, Kunselman AR, Lee PA. Adequacy of a single unstimulated luteinizing hormone level to diagnose central precocious puberty in girls. *Pediatrics*. 2009;123:e1059-e1063.
5. Kaplowitz P, Bloch C, the Section on Endocrinology. Evaluation and referral of children with signs of early puberty. *Pediatrics*. 2016;137:e20153732.

Reference number(s)
1969-A, 2086-A

SPECIALTY GUIDELINE MANAGEMENT

VANTAS (histrelin acetate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Palliative treatment of advanced prostate cancer

B. Compendial Uses
1. Prostate cancer

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Prostate cancer
Authorization of 12 months may be granted for treatment of prostate cancer.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Vantas [package insert]. Malvern, PA: Endo Pharmaceuticals; February 2019.
2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 11, 2018.
3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: prostate cancer. Version 4.2018. http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed October 11, 2018.

Reference number(s)
1918-A, 1919-A

SPECIALTY GUIDELINE MANAGEMENT

ZOLADEX (goserelin acetate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Prostate cancer
   a. For use in combination with flutamide for the management of locally confined stage T2b-T4 (Stage B2-C) carcinoma of the prostate. Treatment with Zoladex and flutamide should start 8 weeks prior to initiating radiation therapy and continue during radiation therapy.
   b. In the palliative treatment of advanced carcinoma of the prostate
2. Endometriosis
   For the management of endometriosis, including pain relief and reduction of endometriotic lesions for the duration of therapy. Experience with Zoladex for the management of endometriosis has been limited to women 18 years of age and older treated for 6 months (Zoladex 3.6 mg strength only)
3. Endometrial thinning
   For use as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding (Zoladex 3.6 mg strength only)
4. Advanced breast cancer
   For use in the palliative treatment of advanced breast cancer in pre-and perimenopausal women

B. Compendial Uses
1. Breast cancer
2. Prostate cancer

All other indications are considered experimental/investigational and are not a covered benefit.

II. EXCLUSIONS

Coverage will not be provided for members with any of the following exclusions: Use of the 10.8 mg strength for diagnoses other than prostate cancer, breast cancer, and gender dysphoria (if applicable).

III. CRITERIA FOR INITIAL APPROVAL

A. Breast Cancer
Authorization of 12 months may be granted for the treatment of HR-positive breast cancer.

B. Prostate Cancer
Authorization of 12 months may be granted for treatment of prostate cancer.

C. Endometriosis
Authorization of 6 months may be granted for treatment of endometriosis.

D. Endometrial-thinning agent
Authorization of 2 doses may be granted for endometrial thinning prior to endometrial ablation for dysfunctional uterine bleeding.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

V. REFERENCES

1. Zoladex 3.6mg [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2017.
2. Zoladex 10.8mg [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2017.
3. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed January 15, 2019.
4. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: breast cancer. Version 3.2018. http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 15, 2019.
5. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: prostate cancer. Version 2.2017. http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed October 11, 2018.
6. Noguchi S, Kim HJ, Jesena A, et al. Phase 3, open-label, randomized study comparing 3-monthly with monthly goserelin in pre-menopausal women with estrogen receptor-positive advanced breast cancer. *Breast Cancer (Tokyo, Japan)*. 2016;23(5):771-779. doi:10.1007/s12282-015-0637-4.

Reference number(s)
1966-A, 2084-A

SPECIALTY GUIDELINE MANAGEMENT

ELIGARD (leuprolide acetate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Palliative treatment of advanced prostate cancer

B. Compendial Uses
1. Prostate cancer
2. Metastatic androgen receptor positive salivary gland tumors

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Prostate cancer
Authorization of 12 months may be granted for treatment of prostate cancer.

B. Salivary gland tumors
Authorization of 12 months may be granted for treatment of metastatic salivary gland tumors when the tumor is androgen receptor positive.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Eligard [package insert]. For Collins, CO: Tolmar Pharmaceuticals; February 2019.
2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 11, 2018.
3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: prostate cancer. Version 4.2018. http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed October 11, 2018.
4. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 11, 2018.

CVS caremark

5. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: head and neck tumors. Version 2.2018. http://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf. Accessed October 11, 2018.